



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Oral Treatment of Hemophilia

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an Exclusive Patent License to ProGenetics, LLC, a company having its headquarters in Blacksburg, Virginia, to practice the inventions embodied in U.S. Patent No. 7,220,718, issued 27 February 2007 (HHS Ref. No. E-281-2001/0-US-03]), European Patent Application No. 02756904.5 (HHS Ref. No. E281-2001/0-EP-04), filed August 2, 2002, and U.S. Patent No. 7,867,974, issued 11 January 2011 (HHS Ref. No. E-281-2001/0-US-05), entitled respectively, “Oral Treatment of Hemophilia” and “Induction of Tolerance by Oral administration of Factor VIII and Treatment of Hemophilia”. The patent rights in these inventions have been assigned to or exclusively licensed to the Government of the United States of America. The prospective Exclusive Patent License territory may be “worldwide”, and the field of use may be limited to:

“Treatment of Hemophilia A and B and immunotolerization using oral delivery methods”.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments and other materials relating to the contemplated Exclusive Patent License should be directed to: Vince Contreras, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4711; Facsimile: (301) 402-0220; E-mail: vince.contreras@nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

This technology relates to therapeutic methods of arresting bleeding episodes in a subject having hemophilia A or B, by orally administering an effective amount of the appropriate clotting factor, sufficient to induce oral tolerance and supply exogenous clotting factor to the subject. Roughly 20,000 people in the U.S. have hemophilia with over 200 new patients born every year. Currently there is no cure for hemophilia and treatment generally involves intravenous infusion of missing clotting factors derived from

concentrated preparations of donated blood plasma which can be expensive and result in generating inhibitory antibodies. The current technology provides a rapid, inexpensive oral treatment for individuals suffering from hemophilia A or B by utilizing a high quantity source of clotting factors produced in milk.

The prospective worldwide Exclusive Patent License will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 16, 2013.

Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer
Office of Technology Transfer,
National Institutes of Health.